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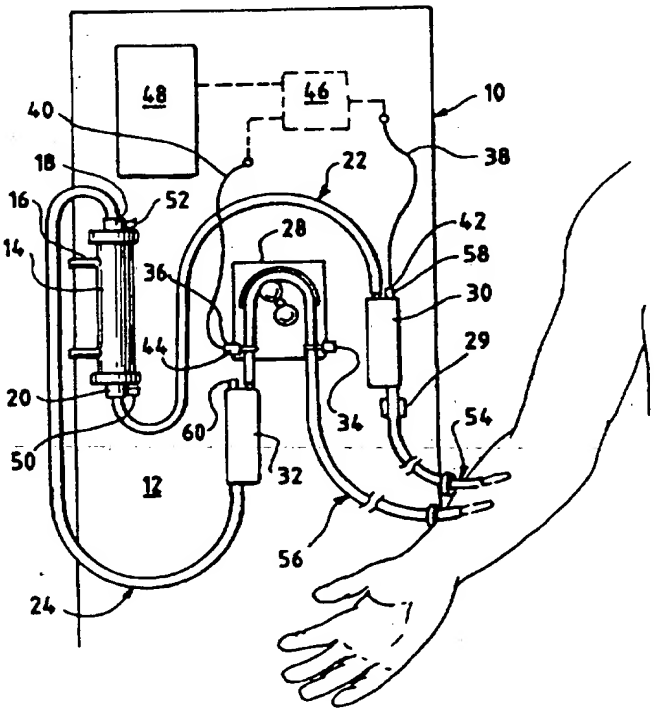
(54) Title: PRESSURE MEASUREMENT IN BLOOD TREATMENT

(57) Abstract

A dialysis system or the like comprises a housing (12) carrying a dialyzer (14) having a blood inlet (18) and a blood outlet (20). Arterial and venous blood tubing sets (24) (22) are provided for respectively conveying blood between the patient and the dialyzer. At least one blood pressure transducer (44) is also provided, the transducer being carried in a connector outside of the housing (12) and connected to an electrical wire (40) for signal communication with an electronic system (46) within the housing, for determining blood pressure from signals sent by the transducer through the wire, and also for displaying the blood pressure so determined. At least one branch connection site (56) is carried on at least one of the blood tubing sets, which site removably receives the connector and transducer in a manner permitting the transducer to measure the pressure of blood in the one tubing set from a position adjacent to the blood in the tubing set.



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PRESSURE MEASUREMENT IN BLOOD TREATMENT

TECHNICAL FIELD

Hemodialysis bloodline pressure measurement by means of long pressure monitoring lines has always been problematic. Monitor lines add complexity and cost to a dialysis bloodline. Furthermore, they inaccurately measure pressures, causing potentially unsafe delays in measurement. Also they clot up, forcing the dialysis procedure to be often interrupted. By this invention, these problems may be eliminated by the elimination of monitor lines.

Originally, extracorporeal blood pressure measurement was very simple. A pillow on the prepump bloodline segment, fitted to a mercury switch device (on a dialysis machine), roughly measured a trigger negative pressure by its collapse. This arrangement did not measure blood pressure accurately, because of both the inherent problems of mercury switches and by the lot-to-lot variation of the pillow's material and shape. The mercury switch turned off the blood pump and activated

a line clamp. For that era's low blood flows of 150-200ml/min as used in dialysis, this was adequate for the situation.

The next evolution involved one or more pressure transducers placed internal to the dialysis machine's faceplate. This transducer (originally electro-mechanical, later electronic) measured blood pressure indirectly via air pressure. An air column within a pressure monitoring tubing assembly ("pressure monitor line") communicated with an air/blood interface within the blood pathway of the blood tubing set. Typically, this air/blood interface was either at a blood chamber, at a "T" line connector, or at an injection site through which a needle made access. The pressure monitor line, either part of the bloodlines or separate therefrom, extended from the air/blood interface component to the machine faceplate. The pressure monitor line ended in a connector which reversibly sealed to, typically, a sterile barrier which in turn reversibly sealed to another connector on the machine face that communicated through the faceplate. Within the machine, other permanent tubing communicated with this connector to the pressure transducer, typically mounted on a circuit board.

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Current dialysis machines have pressure transducers similar in size to a microprocessor. An air column communicates with the air/blood interface via tubing internal and external to the machine, as described above.

A variation on this arrangement is described by the Centry 3 Hemodialyzer of Cobe Laboratories. In this device, the external pressure monitoring line tubing has been largely eliminated. A flattened blood chamber has a flexible diaphragm fitting within a side wall opposite the airspace above the blood level. Outside of the membrane is a port which resealably mates with the machine face connector. The machine face connector communicates with a length of tubing which, in turn, communicates with a pressure transducer within the Centry 3. This invention eliminates the external pressure monitoring line normally running between the faceplate and the blood chamber.

The advantage of these pressure transducer/air column designs is found in that air pressure is measured continuously (rather than just a trigger pressure), and air pressure, though indirect, is more accurate than pillow measurement because it is not subject to lot-to-lot variations of the disposables.

However, many problems are created by these arrangements:

1. The transducer's position in the machine often is at a height different from the patient's heart, creating a pressure head differential from the true air pressure at the air/blood interface. A common height differential can cause a pressure measurement error of up to 20%.

2. The sterile barrier between the sterile space in the bloodline and the unsterile parts of the machine is required to maintain the sterility of the blood pathway. Because of the large volume of air in the air column commonly used, the airflow moving back and forth across the sterile barrier in response to pressure changes requires a large surface area sterile barrier. This large sterile barrier adds a considerable expense. Particularly, in the Centry 3 diaphragmatic arrangement, the surface area is also large and expensive, so as to transmit a relatively large amount of airflow from one side of the diaphragm to the other.

3. The usually present air column is compressible, so the blood level in the air column rises and falls in response to changes in blood pressure. At high flux dialysis positive pressures (blood flows of

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near 500ml/min and air pressures near 450mmHg) blood can rise such that it completely fills the air column up to the sterile barrier. Often the blood clots, requiring the dialysis procedure to be stopped, the lines clamped off, and the sterile barrier replaced.

4. The conventional, long, pressure monitoring lines (arterial and venous), the sterile barrier, and the tubing within the machine from the machine face to the pressure transducer all contribute a pressure drop, causing the recorded pressure to be delayed from the true air pressure at the blood/air interface. In a catastrophic event such as a runaway pump or line-disconnect, such delay could have tragic results.

5. The long, pressure monitoring lines and transducer protectors add complexity, expense and ungainliness to the blood tubing.

It would be beneficial to the dialysis procedure if true blood pressures could be taken and bloodlines simplified. Pressure transducers have been miniaturized to the point where they can be fitted on the end of a wire. Catheters have used such miniature pressure transducers placed on the end of a small bore wire threaded through the inner lumen. These transducers have been used as disposables to measure blood pressures

directly in a blood vessel.

DESCRIPTION OF THE INVENTION

By this invention, a transducer is placed external to the dialysis machine on a wire of sufficient length to connect between the electronic circuit board within the dialysis machine and the desired point on, or preferably within, the blood pathway of the extracorporeal circuit. In this way, the conventional, long column of air between the transducer and air/blood interface is eliminated. The transducer measurement head may be either unsterile or sterile. If unsterile, it will typically measure the air pressure in a tiny airspace behind a tiny diaphragm which is contiguous to the blood pathway. Preferably, there will be essentially no airspace on the blood side. An example of the former comprises a flexible diaphragm on a venous blood chamber adjacent the airspace above the blood level. Preferably, the port provides pressure equalization means so that pressurization of the air space due to the connection of the transducer to the port can be relieved. It further comprises a connector port distal to the diaphragm which may resealably mate

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with the transducer-on-a-wire. An example of the latter comprises a flexible diaphragm on a pump segment connector with one side contiguous to the blood filled blood pathway. It further comprises a port similar to the one described above.

If the transducer face is sterile, it may be inserted through a port on the bloodline to measure blood pressure directly. The port may be an injection site, pre-slit injection site, valve or the like. The transducer may also be threaded up or down within the lumen of the extracorporeal blood pathway to a preferred location. It may also be threaded from such a blood line port through the distal end of the access device (connected to the blood line) into the bloodstream of the patient. The transducer face may be made sterile as a disposable item, but preferably can be reusably sterilized, or it may have a sterile, disposable sheath fitted over the transducer head.

In other words, an extracorporeal blood treatment system, and particularly a dialysis system, comprises a housing carrying a blood treatment unit or dialyzer having a blood inlet and a blood outlet. Arterial and venous blood tubing sets are provided for respectively conveying blood between the patient and the treatment

unit, typically a dialyzer. At least one blood pressure transducer is also provided, the transducer being carried in a connector outside of the housing and connected in signal communication with an electronic system for determining blood pressure from signals sent by the transducer through the wire to it. The electronic system is also capable of displaying the blood pressure to the doctor or other operator of the system.

At least one branch connection set is carried on at least one of the blood tubing sets. The branch connection site removably receives the connector and transducer in a manner permitting the transducer to measure the pressure of the blood in that one tubing set from a position adjacent to the blood in the tubing set.

Thus, the transducer is no longer separated from the blood in which the pressure is being measured by a lengthy conduit having a blood/air interface, as is common in the prior art. Instead, the measurement of the blood pressure is much closer to being a direct measurement, while at the same time, issues of blood clotting in a branch tubing are greatly reduced.

The branch connection typically defines a conduit branching outwardly from tubing of the blood tubing set.

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A flexible diaphragm may be provided to isolate the transducer from blood in the tubing, while permitting the transducer to measure the pressure.

Alternatively, the transducer may extend through the branch connection site into a lumen of the blood tubing of the one set that carries the branch connection site. For example, a catheter may extend through a branch connection site, with the catheter having a distal tip that is positioned within the lumen of the blood tubing. The transducer may be carried adjacent the distal tip, typically in the lumen of the catheter at the distal end, for sensing blood pressure. An electric wire typically connects to the transducer and extends through the catheter, away from the blood tubing into electrical connection with the electronic system.

Alternatively, at least one of the blood sets may carry a blood chamber for removing of gas bubbles and the like. The blood chamber may carry at least one of the branch connection sites, the connector and transducer being received in the blood chamber branch connection site.

The branch connection site may carry a resilient, slit partition of conventional design to provide both sealing from blood leakage and penetration of a probe

through the branch connection site for transducer insertion.

The transducer interface with the blood may be located anywhere on the extracorporeal circuit. That is, either on or in the bloodline, dialyzer or access device, using an AV Fistula needle, dialysis catheter or the like.

The transducer will measure pressures either when the blood is flowing, or with the blood pump off, or with the extracorporeal circuit filled with blood or with another physiologic fluid prior to or after dialysis.

Before and/or after dialysis, the set connection sites can receive a transducer for pressure measurements during processing for storage and reuse. This transducer can either be the same transducer-on-a-wire fitted to the dialysis machine, or a similar transducer-on-a-wire coming from equipment designed for operation in the reuse operation.

Particularly, the transducers and system of this invention may be used to measure pressures in an extracorporeal circuit filled with fluids other than blood. For example, the conditions of flushing and cleaning during reuse of dialysis sets or the like may

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be monitored with the transducer system described, whil antimicrobial wash solution or storage solution is being passed through dialyzers and their blood sets during a procedure for preparing the sets and dialyzers for reuse.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is a substantially diagrammatic, elevational view of a dialysis machine making use of the invention;

Fig. 2 is an enlarged, longitudinal sectional view of a portion of a blood set carried on the apparatus of Fig. 1, showing a branch connector site;

Fig. 3 is an enlarged, longitudinal sectional view of a blood chamber of a blood set shown in Fig. 1;

Fig. 4 is an enlarged sectional portion of a blood set shown in Fig. 1, showing an alternative design of branch connection; and

Fig. 5 shows an enlarged sectional portion of a

blood set of Fig. 1 showing another alternative design of branch connection and a catheter which carries a transducer in accordance with this invention.

DESCRIPTION OF SPECIFIC EMBODIMENTS

Referring to the drawings, Fig. 1 shows a blood dialysis apparatus 10 which may be of generally conventional design except as otherwise indicated herein. Dialysis apparatus 10 comprises a housing 12 which carries a detachable hemodialyzer 14, shown to be of the hollow fiber type. Dialyzer 14 carries hemodialysis solution ports and lines 16, which may be set up in a conventional manner. Hemodialyzer 14 also carries blood ports 18, 20 which respectively connect to blood arterial and venous sets 22, 24, carried by housing 12, to provide a blood circuit that passes from the patient 26 to the dialyzer 14, and then back to the patient again. Conventional roller pump 28 is provided to provide the desired flow of blood through the circuit, and the usual other components for hemodialysis are typically present, although they are deleted from this description for purposes of simplicity. Set 22 extends through conventional bubble detector 29.

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As shown, each hemodialysis set 22, 24 respectively carries a blood chamber 30, 32, which is for the usual function of removing air bubbles, and may be of conventional design. The otherwise conventional blood chambers carry one or more branch connection sites 58, 60 (shown schematically) for the conventional functions of providing optional connection for a heparin line and sterile solution, and, in the prior art, for providing connection to transducer tubing that provides communication between the interior of the respective chambers 30, 32 by an air filled lumen to a transducer which is carried within housing 12.

In accordance with this invention, one or more transducer wires 38, 40 communicate between transducers 42, 44, carried on one wire end, and an electronic system 46, carried in housing 12, which converts in conventional manner signals received from transducers 42, 44 into fluid pressure readings, which may be displayed on readout member 48, carried on housing 12.

Because the respective transducers 42, 44 are positioned in proximity to the pressure they are measuring, improved accuracy in the pressure readout is provided. Also, there is no lag in the readout time in the event of a change of pressure, since there is no

long pneumatic connection between the pressurized area in the set and the transducer, as is current in the prior art. Thus, in the event of a major pressure fluctuation, indicative of a serious problem in the blood flow such as separation of a conduit connection somewhere, the electronic system 46 may be programmed to instantly shut off pump 28 in a manner which is faster than the response time of prior art dialysis pressure sensing systems and faster than the operator can react.

Transducers 42, 44 and their wires 38, 40 may be reusable or replaceable, as may be desired.

Also, the branch connection sites to which the transducers 42, 44 may be connected can be placed at any location desired on the blood circuit. The side connection sites include sites 34, 36 adjacent the roller pump, sites 50, 52 immediately upstream and downstream of the dialyzer, connection sites 54, 56 positioned in various points along the tubing adjacent the patient 26, and connection sites 58, 60. There is no substantial limit as to where connection sites may be placed for the sensing of fluid pressure in the blood circuit.

Fig. 2 shows a branched connection site 56 of generally conventional design carried on the tubing of

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blood set 24. A molded plastic portion 61 connects the separate lengths of tubing 62 of set 24, and also carries a flexible diaphragm 64, which is fluid impermeable, blocking aperture 65 in the sidewall of plastic portion 61. Transducer 44 is carried in a connector housing 66, being connected to wire 40 as previously described, with a face 67 of transducer 44 being accessible to pressures in the blood set. Housing 66 may comprise a male luer or luer lock system, engaging female luer 56. An air space 68 is generally provided between transducer 44 and membrane 64, in connected relation with transducer connector housing 66 causing air space 68 to be sealed. Thus, blood pressures and particularly changes in blood pressure can be sensed by transducer 44 as a function of the pressure defined in air space which, in turn, is governed by the blood pressure on flexible diaphragm 64.

As another embodiment, Fig. 3 shows transducer 44 positioned with its connector 66 in branch connection site 60 of blood chamber 32. Here also a diaphragm 70 may be provided to avoid loss of blood out of port 60, and to prevent blood from entering into contact with transducer 44.

In this particular embodiment, an air space 74 is

conventionally provided in chamber 32, while an air pocket 76 is provided in connection site 60 underneath transducer 44 and above diaphragm 70, as in the previous embodiment, so that diaphragm 70 typically faces air on both sides. In the Fig. 2 embodiment, the inner side of diaphragm 64 is typically in constant contact with the blood.

In both of these embodiments, it can be seen that the transducer 44 is much closer to the actual, pressurized blood than in prior art arrangements, so that an improved, real time readout of fluid pressures in the circuit may be obtained.

Referring to Fig. 4, a blood line 24 is shown, having a branching connector housing 78 connected between sections of the blood lines in series, to branching connection port 80 extending at an acute angle to the axis of the main blood line. Branch connector 80 may carry a partition or plug 82 in a conventional manner, to provide sealing of the system. Plug or partition 82 may carry a slit in known manner to facilitate penetration of a piercing device 84 which may be, a blunt, hollow tube, a piercing device of the type disclosed in U.S. patent No. 5,071,413, or a sharp needle (which does not need a slit to penetrate

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resilient, elastic plug or partition 82).

Transducer 44a, connected to wire 40a, may be carried in or threaded through piercing device 84 to b exposed through the distal end thereof to fluid pressures in set 24. It should be noted in this instance that transducer 44a and the outer portions of piercing devices 84 need to be sterile, at least as to the surfaces that contact blood therein. It can be seen that transducer 44 of the previous embodiments and its carried connector do not have to be sterile because of the protective action of the respective diaphragms 64, 70.

Referring to Fig. 5, another embodiment of branching connector 86 is provided to one of the blood sets 22, 24. Branch connector 86 may be of a generally conventional Y-connector design with a sealing partition 88 and a retention ring 90 to hold partition 88 in place. In this embodiment, a catheter 92 passes through partition 88, which may be slit in a conventional manner. Passage may be facilitated with the use of a known catheter sheath introducer if desired. Catheter 92 carries a transducer 44b at its distal end, with connecting wire 40b extending the length of the catheter, out of set 24 and connecting at the wire end

opposed to the transducer with electronic system 46 of the dialysis machine 10. Such a catheter may be an indwelling catheter, permitting the direct, continuing measurement of blood pressure by transducer 44b, which resides directly in the blood flow path.

Thus, a pressure measuring system is provided for extracorporeal blood circuitry such as dialysis, but also including blood oxygenation, hemoperfusion and the like. This pressure measuring system can give more accurate readouts in shorter time, with less problems of blood clotting than previous designs.

The above has been offered for illustrative purposes only, and is not intended to limit the scope of the invention of this application, which is as defined in the claims below.

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THAT WHICH IS CLAIMED IS:

1. An extracorporeal blood treatment system which comprises a housing carrying a blood treatment unit having a blood inlet and a blood outlet; arterial and venous blood tubing sets for respectively conveying blood between the patient and the treatment unit; at least one blood pressure transducer, said transducer being carried in a connector outside of said housing and connected in signal communication with an electronic system for determining blood pressure from signals sent by said transducer and for displaying said blood pressure; and at least one branch connection site carried by at least one of said blood tubing sets removably receiving said connector and transducer in a manner permitting said transducer to measure the pressure of blood in said one tubing set from a position adjacent to the blood in said tubing set.

2. The system of Claim 1 in which said branch connection site defines a conduit branching outwardly from tubing of said blood tubing set, and a flexible diaphragm to isolate said transducer from blood in said tubing while permitting said transducer to measure said

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pressure.

3. The system of Claim 1 in which said transducer extends through said branch connection site into a lumen of blood tubing of said one set.

4. The system of Claim 3 in which a catheter extends through said branch connection site, said catheter having a distal tip that is positioned within the lumen of said blood tubing, said transducer being carried adjacent said distal tip for sensing blood pressure, said electrical wire extending through said catheter and away from said blood tubing.

5. The system of Claim 1 in which at least one of said blood tubing sets carries a blood chamber, said blood chamber defining at least one of said branch connection sites, said connector and transducer being received at said blood chamber branch connection site.

6. The system of Claim 1 in which said branch connection site carries a resilient, slit partition to provide both sealing from blood leakage and penetration of a probe for transducer insertion.

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7. An extracorporeal blood treatm nt system which comprises a housing carrying a blood treatment unit having a blood inlet and a blood outlet; arterial and venous tubing sets for respectively conveying blood between the patient and the treatment unit; at least one blood pressure transducer, said transducer being carried in a connector outside of said housing and connected to an electrical wire for signal communication with an electronic system for determining blood pressure from signals sent by said transducer through said wire and for displaying said blood pressure; and at least one branch connection site carried on at least one of said blood tubing sets removably receiving said connector and transducer in a manner permitting said transducer to measure the pressure of blood in said one tubing set, said transducer connector being a probe, said probe extending through said branch connection site into a lumen of blood tubing of said one set through a resilient slit partition carried in said branch connection site, to provide both sealing from blood leakage and penetration of said probe whereby said transducer is positioned within the lumen of blood tubing of said one set.

8. The dialysis system of Claim 7 in which said probe comprises a catheter extending through said branch connection site, said catheter having a distal tip which is positioned within the lumen of said blood tubing, said transducer being carried adjacent said distal tip for sensing blood pressure, said electrical wire extending through said catheter and away from said tubing.

9. The system of Claim 7 in which said extracorporeal blood treatment system is a hemodialysis system.

10. An extracorporeal blood treatment system which comprises a housing having a support for carrying a blood treatment unit and attachments for carrying arterial and venous tubing sets for respectively conveying blood between the patient and the treatment unit; at least one blood pressure transducer, said transducer being carried in a connector outside of said housing and connected to an electrical wire for signal communication with an electronic system within said housing for determining blood pressure from signals sent by said transducer through said wire, whereby said

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transducer may removably engage a branch connection sit carried on a blood tubing set to measure the pressure of blood in said tubing set from a position adjacent to the blood in said tubing set.

FIG. 1

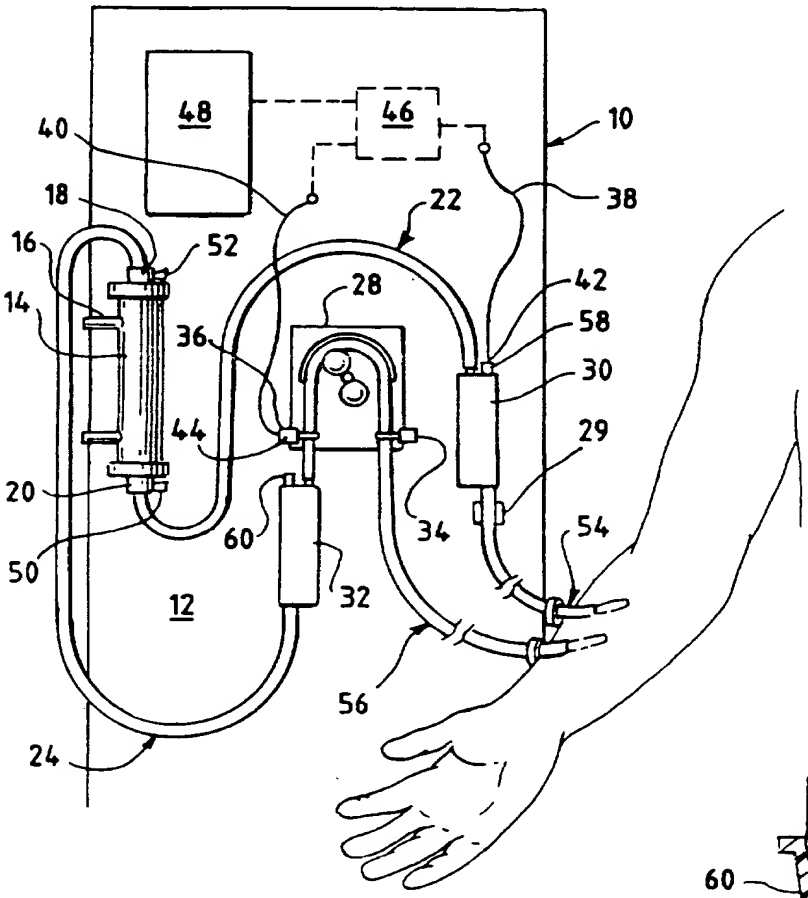


FIG. 5

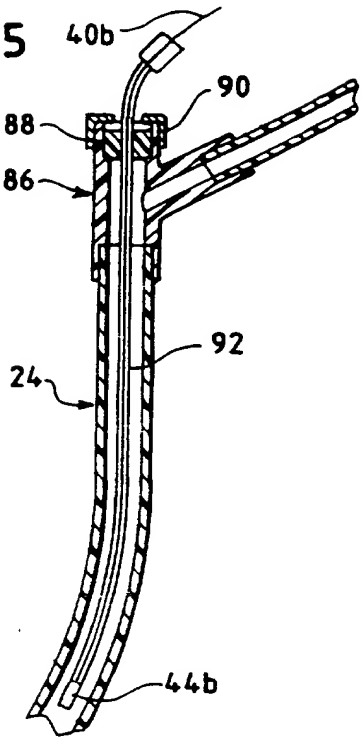


FIG. 3

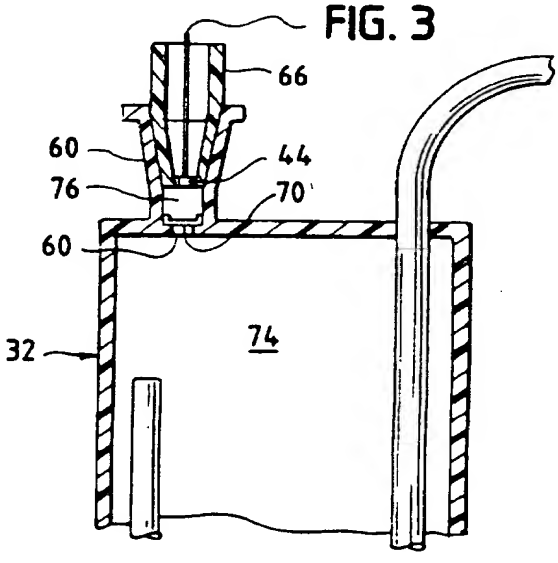


FIG. 2

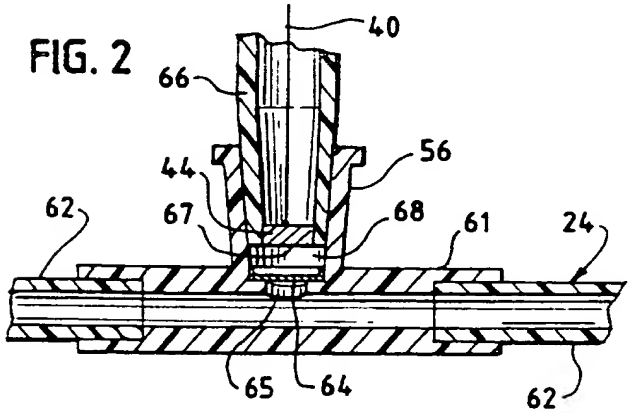
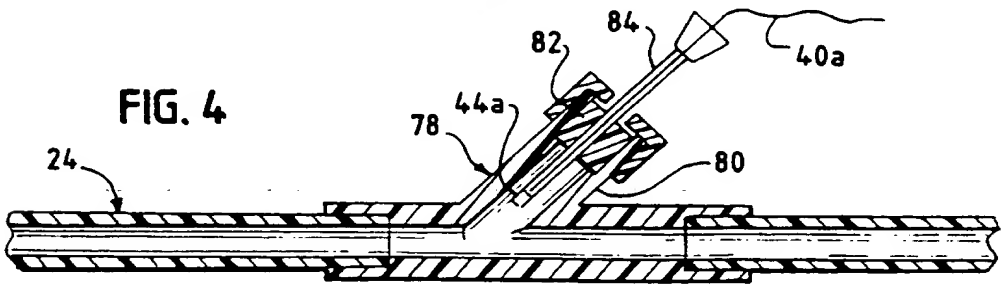


FIG. 4



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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/16472

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/00
US CL :128/673

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/662.06, 667, 673-675; 604/4, 7

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,351,686 A (STEUER et al) 04 October 1994, col. 5, lines 8-15, and figures.	1-5
Y	US 4,431,009 A (MARINO, JR. et al) 14 February 1984, abstract, and columns 4-7.	1-5

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search 20 NOVEMBER 1996	Date of mailing of the international search report 18 DEC 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer STEPHEN HUANG Telephone No. (703) 308-3399

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